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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,186	06/25/2004	Falk Fish	ISA-027.01	5307
63767	7590	07/14/2006	[REDACTED]	[REDACTED] EXAMINER WILLIAMS, DON J
FOLEY HOAG, LLP PATENT GROUP, (w/INVERNESS 155 SEAPORT BLVD. BOSTON, MA 02210-2600			[REDACTED] ART UNIT 2878	[REDACTED] PAPER NUMBER

DATE MAILED: 07/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

2D

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/500,186	FISH ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Don Williams	2878	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 24 April 2006.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1 and 40-43 is/are pending in the application.  
 4a) Of the above claim(s) 2-39 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1 and 40-43 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 25 June 2004 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/24/06</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

Applicant's argument with respect to claims 1, 40-43 have been considered but are moot in view of new ground(s) of rejection. Claims 2-39 have been cancelled.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, and 40-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen (5,580,794) in view of Rice et al (4,906,100).

As to claim 1, Allen discloses a lateral flow strip (10) configured to receive a sample (liquid) and comprising a detection zone (16) configured to immobilize a fluorescent compound (liquid), a presence or absence of the fluorescent compound (liquid) being indicative of the presence or absence of an analyte in a sample (liquid) received by the lateral flow strip (10), a light source (18) configured to excite fluorescence from the fluorescent compound (liquid) if present in the detection zone (16), a first plurality of detector elements (20, 22), each detector element (20, 22) of the first plurality of detectors elements (20, 22) being configured to receive fluorescence from a respective portion of the detection zone (16), and wherein the photodetectors (20, 22) are configured to produce one photodetector signal indicative of fluorescence (liquid) received by the photodetectors (20, 22), and a processor (32) configured to

receive one photodetector signal and to determine the presence or absence of the analyte based on the photodetector signal, (see figure 2, column 8, lines 1-25, figure 5, column 11, lines 3-35, figure 3, column 12, lines 7-67, figure 8, column 14, lines 1-12). Allen and Rice et al are related in that they teach detecting extremely dilute concentrations of the sample by measuring the reflected light from the sample.

Allen fails to explicitly teach a two dimensional photodetector. Rice et al teach that (see column 3, lines 50-55) a camera or photometer can be employed to detect the fluorescent signal from the sample. It would have been obvious for one ordinary skill in the art to modify Allen to include a camera as taught by Rice et al since they are functionally equivalent and the camera would also provide an image of the signal.

As to claim 40, the modified Allen discloses the lateral flow strip (10) comprising a control zone (38) configured to immobilize the fluorescent compound (liquid) regardless of the presence of the analyte in the sample received by the lateral flow strip (10), a light source (18) is further configured to excite fluorescence from the fluorescent compound (liquid) if present in the control zone (38), a second plurality of detector elements (20, 22) and each detector element (20, 22) of the second plurality of detector elements (20, 22) is configured to receive fluorescence from a respective portion of the control zone (38, 40, 42), (see figure 2, column 8, lines 1-25, figure 5, column 11, lines 3-35, figure 3, column 12, lines 7-67, figure 8, column 14, lines 1-12). Allen fails to explicitly disclose a two dimensional photodetector. Rice et al disclose a camera capable of detecting fluorescent signal. It would have been obvious for one ordinary skill in the art to modify Allen to include a camera equivalent to a two dimensional

photodetector as disclosed by Rice et al to improve the capability of detecting fluorescent signal from the sample.

As to claim 41, the modified Allen discloses the control zone (38) is spaced apart from the detection zone (40, 42), (see figure 3, column 12, lines 7-67).

As to claim 42, the modified Allen discloses a light source, the two dimensional photodetectors, the processor, and the power source, (see figure 2, column 8, lines 1-25). Allen fails to explicitly disclose 120mW of power. However, the exact power supply used would have been obvious for one ordinary skill in the art in order to improve the optimal performance of the device.

As to claim 43, the modified Allen discloses a plurality of light sources (66, 70) and each light source (66, 70) of the plurality of light sources (66, 70) is configured to excite fluorescence from a respective region (60, 62, 64) of the lateral flow strip (54), (see figure 5, column 11, lines 3-35).

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Don Williams whose telephone number is 571-272-8538. The examiner can normally be reached on 8:30a.m. to 5:30a.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Georgia Epps can be reached on 571-272-2328. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Georgia Epps  
Supervisory Patent Examiner  
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